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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/992,914	12/18/1997	EIJIRO WATANABE	0020-4348P	4405

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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/992,914

Applicant(s)

WATANABE ET AL.

Examiner

David H Kruse

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,6,7,9,11-13,15-18,30-36,40,41,43 and 44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6 is/are allowed.
- 6) ☒ Claim(s) 1,4,7,9,11-13,15-18,30-36,40,41 and 44 is/are rejected.
- 7) ☒ Claim(s) 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

STATUS OF THE APPLICATION

Continued Examination Under 37 CFR § 1.114

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 28 May 2003 has been entered.
2. Claims 1, 4, 6, 7, 9, 11-13, 15-18, 30-36, 40, 41, 43 and 44 are pending in the instant application.
3. The pending rejection under Double Patenting over copending application 09/612,095 is now moot, said copending application has been abandoned.
4. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendment filed 28 May 2003.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Drawings

6. The markup version of Figure 1, filed 14 April 2000 is informal. Formal drawings are required in response to this Office action. See the PTO-948 attached to Paper No. 9, mailed 15 September 1999, a copy is attached hereto. Applicant is reminded that correction of the drawings cannot be held in abeyance, and that formal drawings are required in response to this Office Action as outlined in 37 CFR § 1.85(a). Failure to

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take corrective action within the set period will be considered non-responsive to this Office action.

Claim Objections

7. Claims 43 and 44 remain objected to because of the following informalities:

At claims 43 and 44 the phrase "An isolated nucleic acid of claim 1" should read -

- The isolated nucleic acid of claim 1 --. Appropriate correction is required.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 9, 12, 13, 17, 18 and 44 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a substantial asserted utility or a well-established utility.

The specification discloses nucleic acid sequences that encode putative raffinose synthase enzymes (SEQ ID NOs. 4, 6 and 8). The specification asserts that these nucleic acid sequences encode raffinose synthase (pages 9-10 of the Specification, filed 14 April 2002). However, Applicant has provided no evidence to substantiate the assertion that the encoded protein having the amino acid sequence of SEQ ID NO: 4, 6 or 8 functions as raffinose synthase. There are no working examples to demonstrate what specific function the encoded polypeptide having the amino acid sequence of SEQ ID NO: 4, 6 or 8 will have upon expression in a transgenic host cell. Applicant has not provided evidence of function of polypeptides having the amino acid sequence of SEQ ID NO: 4, 6 or 8. The art teaches that one of skill in the art cannot assume the function

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of the polypeptide encoded by an isolated nucleic acid solely based on sequence similarity to a known polypeptide sequence (see Duggleby 1997, . . . , and Richmond *et al* 2000, Plant Physiology 124: 495-498, see paragraph spanning left and right column on page 497). In addition, the art teaches that raffinose synthase enzymes have high overall amino acid sequence homology with seed imbibition proteins and stachyose synthases, hence amino acid sequence similarity cannot be used to assert function (see Peterbauer *et al* 2002, Planta 215: 839-846, see page 840, left column and page 841, right column).

Consequently, Applicant has failed to define a substantial utility for the claimed nucleic acids encoding the amino acid sequence of SEQ ID NO: 4, 6 or 8, hence, a well-established utility is not known.

Claim Rejections - 35 USC § 112

Claims 9, 12, 13, 17, 18 and 44 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

10. Claims 1, 4, 7, 9, 11-13, 15-18, 30-36, 40, 41 and 44 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last

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Office action mailed 29 August 2002. Applicant's amendment filed 28 May 2003 does not present any new arguments to this rejection.

The teachings of Peterbauer *et al* 2002 are outlined above. The art teaches that one of skill in the art cannot describe a raffinose synthase, or the nucleic acid that encodes it, based on amino acid sequence similarity with a known raffinose synthase. Hence, it remains unclear that Applicant has actually describes nucleic acids that encode a raffinose synthase at SEQ ID NO: 4, 6 or 8. If Applicant is able to provide evidence of function of the describe nucleic acids, then it is the Examiner's opinion that the description of such nucleic acid does not adequately describe other nucleic acids that hybridize to said sequences as broadly claimed in claims 1, 30, 32 and 36.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. At 1406, the court states that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. In the instant case, Applicant does not describe structural features common to the members of the claimed genus.

See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

11. Claims 1, 4, 7, 9, 11-13, 15-18, 30-36, 40, 41 and 44 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding the amino acid sequence of SEQ ID NO: 2, a chimeric nucleic acid comprising said isolated nucleic acid, a transformant comprising said chimeric nucleic acid, a plasmid comprising said nucleic acid, a host organism either a microorganism or plant comprising said plasmid and a method of metabolic modification of a plant comprising introducing said isolated nucleic acid, does not reasonably provide enablement for an isolated nucleic acid encoding the amino acid sequence of SEQ ID NO: 4, 6 or 8, or an isolated nucleic acid that hybridizes with a complement to said isolated nucleic acid isolated from any leguminous, lamiaceous or monocotyledonous plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant has only provided evidence of function for a polypeptide having the amino acid sequence of SEQ ID NO: 2 and isolated nucleic acid that encode said polypeptide. The art teaches that one of skill in the art cannot assume the function of the polypeptide encoded by an isolated nucleic acid solely based on sequence similarity to a known polypeptide sequence (see Duggleby 1997, *Plant Physiology* 114: 1000-1005, and Richmond *et al* 2000, *Plant Physiology* 124: 495-498, see paragraph spanning right and left column on page 497). In addition, the art teaches that raffinose synthase enzymes have high overall amino acid sequence homology with seed imbibition proteins and stachyose synthases, hence amino acid sequence similarity cannot be used to assert function (see Peterbauer *et al* 2002, *Planta* 215:839-846, see page 840, left column and page 841, right column). Hence, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to make and use the genus of nucleic acids claimed and to isolate others within the scope of claims 1, 30, 32 and 36, and confirm their function in order to make and use the claimed vectors and transgenic organisms.

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12. Claims 1, 4, 7, 11, 15, 16 and 30-36 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 1, subsections (i), (j), (k) and (l), the terms "obtainable", "hybridizable" and "amplifiable" render the claim indefinite because the terms are indefinite limitations and do not state the metes and bounds of the claimed invention. Claims 4, 7, 11, 15 and 16 are also indefinite because they do not obviate the indefiniteness of said terms in claim 1.

At claims 30, 32 and 36, subsections (i), (j), (k) and (l), the terms "obtainable", "hybridizable" and "amplifiable" render the claim indefinite because the terms are indefinite limitations and do not state the metes and bounds of the claimed invention. Claims 31 and 33-35 are also indefinite because they do not obviate the indefiniteness of said terms in claim 1.

Double Patenting

13. Claims 1, 4, 7 and 30-36 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 16-22 and 28-30 of copending Application No. 09/301,766. This rejection is repeated for the reason of record as set forth in the last Office action mailed 29 August 2002, and has been modified in view of the amendment to the claims the instant application and said copending application.

Conclusion

14. The claims are free of the prior art, which neither teaches nor suggests the claimed isolated nucleic acids encoding a raffinose synthase enzyme. The rejection under 35 USC § 102(e) over Osumi *et al* (US Patent 6,166,292) is withdrawn in view of *In re Hilmer, Korger, Weyer, and Aumuller*, 149 USPQ 480 (CCPA 1966).

15. Claim 6 is allowed.

16. Claim 43 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

17. Claims 1, 4, 7, 9, 11-13, 15-18, 30-36, 40, 41 and 44 remain rejected.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'David H. Kruse', is written over the printed name and date.

David H. Kruse, Ph.D.
15 August 2003